K140660
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JUN 2 4 2014

5 510(K) SUMMARY

5.1 510(K) OWNER

Mobius Medical Systems, LP
5012 Tamarisk St
Bellaire, TX 77401
Tel: (888) 263-8541
Fax: (888) 263-8541

5.2 CONTACT PERSON

Stan Eshelman

5.3 PREPARATION DATE

March 12, 2014

5.4 TRADE NAME

Mobius3D

5.5 COMMON NAME

Secondary Check QA Software

5.6 CLASSIFICATION NAME

Accelerator, Linear, Medical
21 CFR 892.5050
Product Code - IYE

5.7 PREDICATE DEVICES

- K072374 COMPASS (Scanditronix Wellhöfer)
- K032886 Diamond Setup 2000 (K&S Assoc., Inc.)

5.8 DEVICE DESCRIPTION

Mobius3D is a software product used within a radiation therapy clinic for quality assurance and treatment plan verification. It is important to note that while Mobius3D operates in the field of radiation therapy, it is neither a radiation delivery device (e.g. a linear accelerator), nor is it a treatment planning system (TPS). Mobius3D cannot design or transmit instructions to a delivery device, nor does it control any other medical device. Mobius3D is an analysis tool meant solely for quality assurance (QA) purposes when used by trained medical professionals. Being a software-only QA tool, Mobius3D never comes into contact with patients

Mobius3D performs dose calculation verifications for radiation treatment plans by doing an independent calculation of radiation dose. Radiation dose is initially calculated by a treatment planning system (TPS), which is a software tool that develops a detailed set of instructions (i.e. a plan) for another system (e.g. a linear accelerator) to deliver radiation to a patient. The dose calculation performed by Mobius3D uses a proprietary collapsed cone convolution superposition (CCCS) algorithm.

Mobius3D also performs dose delivery quality assurance for radiation treatment plans by using the measured data recorded in a linear accelerator's delivery log files to calculate a delivered dose. This is presented to the end user in a software component of Mobius3D called MobiusFX. The MobiusFX component is available to users through licensing as an add-on to the core Mobius3D software features.

5.9 Indications for Use

Mobius3D software is used for quality assurance and treatment plan verification in radiation therapy. It calculates radiation dose three-dimensionally in a representation of a patient or a phantom. The calculation is based on read-in treatment plans that are initially calculated by a treatment planning system, and may additionally be based on external measurements of radiation fields from other sources such as linac delivery log data.

Mobius3D is not a treatment planning system. It is only to be used by trained radiation oncology personnel as a quality assurance tool.

5.10 Technological Characteristics Summary

The principle technological characteristic of Mobius3D and its predicate devices is to perform quality assurance evaluations on the radiation treatment planning system (TPS) and radiation delivery system (e.g. linear accelerator). Detailed technological characteristics and indications for use presented within the full set of submitted documentation for this 510(k) application support the claim that Mobius3D is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Mobius Medical Systems, LP
Stan Eshelman
5012 Tamarisk St.
BELLAIRE TX 77401

June 24, 2014

Re: K140660
Trade/Device Name: Mobius3D
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 1, 2014
Received: May 05, 2014

Dear Mr. Eshelman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140660

Device Name: Mobius3D

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara